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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/186,810 11/05/98 CARLYLE

W S16.12-0052

EXAMINER

QM12/1114

PREBILIC, P

ART UNIT

PAPER NUMBER

3738

DATE MAILED:

11/14/00

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/186,810

Applicant(s)
Carlyle et al

Examiner
Paul Prebille

Group Art Unit
3738



☒ Responsive to communication(s) filed on Sep 8, 2000

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1, 3, 4, and 8-17 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1, 3, 4, 8-13, and 15-17 is/are rejected.

☒ Claim(s) 14 is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3, 4, and 8-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With regard to claims 1, 3, 4, and 8-17, it is unclear whether "characteristic of . . ." of claim 1, line 4 is positively limiting the claims to these specific types or whether they are merely examples. For this reason, the claim language will be interpreted broadly as including many bonding types as set forth on page 16.

With regard to claims 3 and 4, they are dependent upon canceled claim 2, and thus, their scopes are indefinite. For this reason, the Examiner will interpret them as if they are dependent upon claim 1 when evaluating them on their merits.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 1, 11, 15, and 16 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Muller-Lierheim (US 4,828,563); see the entire document.

Claims 1, 3, 8, 9, 11, 12, 15, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Guire (US 5,263,992); see the entire document wherein human tissue can be used as the substrate and growth factors can be used as the bioactive agents.

Claims 1 and 3-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Noishiki (EP 0742020) wherein attaching growth factors with glutaraldehyde was known and used in the prior art of Noishiki. Since the bonding need not be covalent but can be by non-covalent bonding which apparently includes hydrogen bonding, van der Waals interactions, ionic interactions, and molecular rearrangements, the claim language is fully met.

Claims 1, 3, 4, 8, 9, 12, 13, and 15-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Bayne et al (EP 0476983) wherein the fibrin is used to associate the growth factor with the substrate; see the whole document especially page 8.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Muller-Lierheim in view of Weatherford et al (article entitled "Vascular Endothelial Growth Factor . . . "). Muller-

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Lierheim discloses attaching growth factors to implants but fails to teach attaching vascular endothelial growth factor to a substrate as now claimed. Weatherford et al teaches that it was known to attach VEGF to similar implants. Hence, it is the Examiner's position that it would have been obvious to one of ordinary skill in the art to attach a VEGF to the Muller-Lierheim implant in order to promote vascular endothelial cells ingrowth thereon.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Guire (US 5,263,992) in view of Goldstein (US 5,613,982). Guire discloses the use of human tissue as the implant substrate material but fails to disclose the use of animal tissue therefor. Goldstein, however, teaches that it was known to use porcine tissue for similar implants. Hence, it is the Examiner's position that it would have been obvious to use porcine tissue as the tissue substrate of Guire in order to reduce the cost of the implant and in order to reduce the risk of disease transmission to human beings upon implantation.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bayne et al (EP 0476983) alone. Bayne et al (EP) meets the claim language except for the sterilizing and packaging of the implant as claimed. However, the Examiner hereby gives official notice that sterilizing and packaging of medical materials for distribution has been known to the art. Therefore, it is the Examiner's position that it would have been obvious to an ordinary artisan to sterilize and package the claimed invention so that patients all over the world could benefit from it.

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Claim 14 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments filed September 8, 2000 have been fully considered but they are not persuasive.

In response to the traversal of the Muller-Lierheim 35 USC 102(b) that the growth factors stimulate association of viable cells with the polymer, the Examiner respectfully disagrees and takes the position that Muller-Lierheim clearly implies and explicitly suggests that cell growth into the substrate is stimulated by the growth factor thereof; see column 1, lines 50-64.

Applicant next traversed the Guire 35 USC 102(b) rejection by stating that the linker molecule is not a crosslinking molecule. In response, the Examiner posits that the linker molecule is a crosslinker molecule to the extent required by the claim language because it has two reactive ends; this is a definition of a crosslinking molecule. In addition, contrary to Applicant's arguments, the claims do not require that the crosslinking agent be bound at both ends to the substrate.

Next, Applicant traverses the Noishiki 35 USC 102 rejection by stating that the substrate is not coated with the growth factor, but rather, the biocompatible material is. In response, the Examiner posits that the substrate can be the coating wherein the coating is part of the substrate.

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In response to Applicant's traversal of the Bayne et al 35 USC 102 rejection that the attachment of growth factor to the substrate is not via the covalent or non-covalent means set forth in the claims, the Examiner posits that the means of attachment used in Bayne et al falls within the non-covalent category since the language used is not clearly positively limiting.

As to the traversals of the 35 USC 103(a) rejections, the Examiner notes that Applicant basically relies on the distinctions set forth in the traversals of the 35 USC 102 rejections. For this reason, the Examiner hereby incorporates the rationale used therein to address the argument presented against the present rejections.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Prebilic whose telephone number is (703) 308-2905. The examiner normally be reached on Monday-Thursday from 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vincent Millin, can be reached on (703) 308-1065. The fax phone number for this Technology Center is (703) 305-3580.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 3700 receptionist whose telephone number is (703) 308-0858.



Paul Prebilic
Primary Examiner
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